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A Phase 1 Multicenter Dose Escalation and Dose Expansion Study of the study drug MYTX-011 in Subjects with Non-Small Cell Lung Cancer Cell Lung Cancer – KisMET-01

Submission date
27/10/2023

Recruitment status
Recruiting

Registration date
02/04/2024

Overall study status
Ongoing

Last Edited
22/07/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this research is to determine the safety and tolerability, and to aid in the selection of the best dose for future development, as well as measure any antitumour activity of a new antibody drug conjugate (ADC) called MYTX-011. MYTX-011 is a new drug, being studied in humans for the first time for treatment of advanced non-small cell lung cancer (NSCLC). The study team is investigating this drug to help treat lung cancers that are resistant to standard medications. This drug targets a protein called cMET on the cancer cell. MYTX-011 will attach to the cMET and release chemotherapy into the cancer cell.

Who can participate?
Patients with advanced non-small cell lung cancer (NSCLC)

What does the study involve?
Not provided at time of registration

What are the possible benefits and risks of participating?
Benefits:
Not provided at time of registration
Risks:
MYTX-011 has not been tested in humans previously and the safety profile is unknown at this time. The likelihood of these risks occurring is unknown.

Transient and Reversible Side Effects of MYTX-011 Observed in Cynomolgus Monkeys Included:
• Neutropenia (decrease in neutrophils counts (component of white blood cells))
• Decrease in reticulocytes (immature red blood cells) and red blood cell mass
• Leukopenia (low white blood cell count as a result of Neutropenia)
• Anaemia (low red blood cells)
• Increased AST levels (liver enzymes)

MYTX-011 is part of a family of drugs called Antibody-Drug Conjugates (ADC). The risks associated with this family of drugs is listed below.

Antibody Drug Conjugates

- Hypoalbuminemia
- Peripheral edema
- Infusion related reactions
- Anaphylaxis (severe allergic reaction)
- Hematologic (blood) toxicities
- Myelosuppression (decrease in bone marrow activity, reduced production of blood cells)
  - o Anemia (decrease in red blood cells),
  - o Neutropenia or lymphopenia (decrease in white blood cells)
- Hemorrhage (release of blood from a blood vessel)
- Eye disorders
- Peripheral neuropathy (damage to the nerves, can cause numbness)
- Serious infections
- Pulmonary toxicity (lung damage)
- Hepatotoxicity (liver damage)
- Hyperglycemia (high blood sugar)
- Serious dermatologic (skin) reactions
- Infusion site extravasation (drug leakage from blood vessels)
- Progressive multifocal leukoencephalopathy (disease of white matter of the brain)
- Gastrointestinal (digestive) complications (e.g. nausea, vomiting, and diarrhea)
- Tumour lysis syndrome (release of tumor cell contents into the bloodstream)
- Embryo fetal (pregnancy) toxicity (toxic effects on an unborn baby)

Risks of Blood Draws

- Pain, swelling, or bruising around the vein where the blood is drawn
- Dizziness or fainting
- Infection

Risks of ECGs

- Irritation from adhesive pads placed on skin during ECG

Risk of Intravenous Infusion

- Pain, swelling or bruising around the vein of the infusion site

Risks of Tumor Biopsy

A biopsy is only required (Part 2) if a sample of a previous biopsy is not available for lab testing. There are also visits that have optional tumour biopsy collections.

Fine Needle Aspiration

- o Pain, swelling or bruising around needle entry site

Core Biopsy

- o Scarring from incision
- o Pain, swelling or bruising from needle entry site
- o Bleeding at incision/ entry site
- o Infection at entry site
- o Allergic reaction to anesthetic used to numb the skin

Risks of CT Scan

- Allergic reaction to contrast material - Participants will be asked questions and may undergo

tests to ensure that the CT contrast material is safe
• Pain, swelling, or bruising at needle entry site for contrast injection
• Discomfort during procedure as patients are asked not to move for an extended duration of time
• Risk of kidney damage from the dye especially if the patient is dehydrated or already have kidney problems

Risk of Eye Exams
During the slit lamp exam, a bright light will be used to look at participants eyes which may be uncomfortable.
Eyes may be sensitive to light when they are dilated after eye drops are applied by the study doctor. The doctor may give dark glasses to wear to help with light sensitivity.
One part of the eye exam may use a dye to help the doctor look at participants eyes. There is a risk a participant could have an allergic reaction to the dye.

Radiation Exposure (see below)
Risks of MUGA Scan
• Pain, swelling, or bruising at needle entry site for injection of the radioactive tracer
• Radiation Exposure (see below)

Risks of Radiation used in CT and MUGA scans:
Ionising radiation may cause cancer many years or decades after the exposure. Participants in their current clinical condition have an extremely small chance of this occurring.

Risks of MRI Scan
• Allergic reaction to contrast material, although serious reactions are very rare
• Pain, swelling, or bruising at needle entry site for contrast injection
• Claustrophobia
• Risk from metal artefacts in the participants body
• Participants will be asked questions to ensure that the MRI scan is safe for them.

Unknown Risks
In addition to these risks, taking part in this research may harm the participant in unknown ways. MYTX-011 has not been tested previously in humans and there may be additional side effect not yet known.

Pregnancy Risks
Taking part in this study may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death. Study participants are required to agree to use highly effective birth control methods and report any pregnancies or partner pregnancies to the study team immediately.

Where is the study run from?
Catalyst Clinical Research LLC (UK)

When is the study starting and how long is it expected to run for?
November 2023 to March 2028

Who is funding the study?
Mythic Therapeutics (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05652868

Integrated Research Application System (IRAS)
1007533

Protocol serial number
MYTX-011-01

Study information

Scientific Title

A Phase 1 Multicenter Dose Escalation and Dose Expansion Study of Antibody-Drug Conjugate MYTX-011 in Subjects with Non-Small Cell Lung Cancer – KisMET-01

Acronym
MYTX-011-01

Study objectives
OBJECTIVES FOR PART 1: MYTX-011 DOSE ESCALATION
1. To evaluate the safety and tolerability of MYTX-011
2. To determine the recommended Phase 2 dose (RP2D) and/or maximum tolerated dose (MTD) of MYTX-011

Part 2:
To evaluate preliminary anti-tumor activity of MYTX-011 in subjects with the following:
Cohort A: Advanced nonsquamous NSCLC, with high cMET expression, without actionable EGFR mutations
Cohort B: Advanced non squamous NSCLC, with intermediate cMET expression, without actionable EGFR mutations
Cohort C: Advanced squamous cell NSCLC, with cMET overexpression without actionable EGFR mutations
Cohort D: Advanced squamous or non-squamous NSCLC with MET amplification or exon 14 skipping mutations without actionable EGFR mutations
Cohort E: Advanced squamous or non-squamous NSCLC with cMET expression without actionable EGFR
mutations and previously received cMET ADC or antibody therapy

SECONDARY OBJECTIVES FOR PART 1: MYTX-011 DOSE ESCALATION
1. To characterize the pharmacokinetic (PK) profile of MYTX-011, including total ADC, total antibody, and free MMAE
2. Determine the optimal biological dose of MYTX-011 in Cohort A: based on safety, PK, and preliminary anti-tumor activity
3 To assess the incidence and persistence of anti-drug antibodies (ADA) to MYTX-011
4. To determine preliminary anti-tumor activity of MYTX-011

SECONDARY OBJECTIVES FOR PART 2: MYTX-011 DOSE EXPANSION (COHORTS A-E)
1 To evaluate the safety and tolerability of MYTX-011
2. To characterize the PK profile of MYTX-011, including total ADC, total antibody, and free MMAE
3. To characterize anti-tumor activity of MYTX-011
4. To explore the optimal biological dose of MYTX-011 in Cohort A
5. To assess the incidence and persistence of ADA to MYTX-011

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/01/2024, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8155; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0246

Primary study design

Interventional

Study design
Interventional dose escalation and dose expansion study with randomized dose

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Non-Small Cell Lung Cancer

Interventions
Part 1- Dose Escalation

Subjects in Part 1 will be enrolled to evaluate the safety of escalating doses of MYTX-011 and to establish the recommended Phase 2 dose (the dose that will be used for the next phase of the study, (RP2D)). A safety review team will review the data during this part to ensure safety of subjects prior to increasing the dose to the next level. The dose escalation phase of the study aims to examine up to 7 dosing levels.

Part 2 – Dose Expansion

Once the RP2D is established from the Part 1 – Dose Escalation portion of the study, Part 2 - Dose Expansion will begin. Subjects in Part 2 will be assigned to a cohort by the amount of cMET on their tumour and what type of NSCLC they have. cMET is a protein on the tumour. The level of cMET (otherwise known as “expression”)will be determined by a lab test called IHC (immunohistochemistry). A previously removed section of the subjects tumour will be used to run a lab test to determine this level and place the subject in the correct cohort. If a previously removed section of the tumour is not available, the subject will be asked to undergo a biopsy.

- Cohort A: Non-squamous NSCLC with high cMET expression. If the subject is selected to be in Cohort A you will be randomised to one of 2 dose levels of MYTX-011. Randomised means there is a 50/50 chance the subject will be placed in either dose level at random, the subject will not be able to choose, like flipping a coin. This process improves the scientific validity of the study.
- Cohort B: Non-Squamous NSCLC with intermediate cMET expression
- Cohort C: Squamous cell NSCLC with cMET overexpression
- Cohort D: cMET expression that does not meet inclusion criteria for Cohorts A, B, or C, and with MET amplification or exon 14 skipping mutation (these are DNA changes determined separately)
- Cohort E: cMET expression by IHC and previously received cMET targeted ADC or antibody therapy
- There will be only one dose per cohort for Cohorts B-E

All subjects in Parts 1 and Part 2 will be dosed on a 21-day cycle until disease progression, unacceptable toxicity, voluntary withdrawal, or end of treatment, whichever occurs first.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
MYTX-011

Primary outcome(s)
Part 1: MYTX-011 Dose Escalation
1. Incidence and severity of TEAEs, AEs, and clinically significant changes from baseline in vital signs, ECGs, and
laboratory parameters
2. The RP2D will be selected as a biologically active dose at or below the MTD (or the highest dose tested if the
3. MTD is not identified during the study) MTD will be determined by DLTs during Cycle 1. The observation period for DLTs is Cycle 1.

Part 2: MYTX-011 Dose Expansion (Cohorts A-E)
1. ORR (confirmed CR+PR) in each expansion cohort according to RECIST 1.1 at Screening, Cycles 2 and 4 at day 1, Cycle 5 for 2 years, End of Trial, Long Term Survival Follow-up.

Key secondary outcome(s)
PART 1 DOSE ESCALATION
1. Pharmacokinetic values for MYTX-011 including but not limited to total antibody, conjugated payload, and free payload (maximum concentration [Cmax], time to maximum concentration [Tmax], last measurable concentration [Clast], time to last measurable concentration [Tlast], area under the concentration-time curve [AUC], half-life, total clearance [CL], volume of distribution at steady state [Vss]) at Cycles 1 and 3 (D1, D2, D4, D8, D15), Cycles 2 and 4 (D1), C5-2 years (D1), End of Trial.
2. Presence of anti-drug antibodies at Cycles 1 and 3 (D1), Cycles 2 and 4 (D1), C5-2 years (D1), End of Trial.
3. Objective response rate (ORR; confirmed complete response [CR] + confirmed partial response [PR]) using RECIST 1.1at Screening, Cycles 2 and 4 (D1), C5-2 years (D1), End of Trial, Long Term Survival Follow-Up.
Note: CR and PR must be confirmed by 2 tumor imaging assessments conducted at least 4 weeks apart.
4. Duration of response (DOR) for subjects who achieve a confirmed CR or PR
5. Time to response
6. Best overall response
7. Disease control rate (DCR; confirmed CR+PR+stable disease [SD]),
Note: SD must occur at least ≥ 6 weeks following the first dose of MYTX-011 administration.
8. Progression free survival (PFS)
9. Overall survival (OS)
10. Biomarkers and predictors of response and resistance to MYTX-011 in tumor and blood at Cycles 1 and 3 (D1), Cycles 2 and 4 (D1), C5-2 years (D1), End of Trial.

PART 2 DOSE EXPANSION
Efficacy assessments according to RECIST 1.1 in each expansion cohort at Screening, Cycles 2 and 4 (D1), C5-2 years (D1), End of Trial, Long Term Survival Follow-up., including:
1. Duration of response (DOR) for subjects who achieve confirmed CR or PR
2. Time to response
3. Best overall response
4. Disease control rate (confirmed CR+PR+SD)
5. Progression free survival (PFS)
6. OS

7. Incidence and severity of TEAEs, treatment-related AEs, and clinically significant changes from baseline in vital signs, ECGs parameters, and laboratory parameters
8. PK values for MYTX-011 including but not limited to total antibody, conjugated payload, and free payload (Cmax, Tmax, Clast, Tlast, AUC, half-life, CL, Vss)
9. Presence of ADA at multiple timepoints during the study

Completion date
31/03/2028

Eligibility

Key inclusion criteria
Subjects must meet all the following inclusion criteria to be eligible for participation in this study:
1. Part 1:
a. Have histologically or cytologically confirmed locally advanced, recurrent (and not a candidate for curative therapy), or metastatic NSCLC and have received available standard of care therapy.
b. There is no limit on the number of prior therapies that can have been received.
2. Part 2 (Cohorts A-E):
a. Known to not have an actionable EGFR mutation. Subjects with or without other driver mutations are permitted to enroll.
b. Must have received available standard of care therapy.
c. Must have progressed on at least 1 line of prior therapy in the locally advanced/metastatic setting. Note: multiple lines of tyrosine kinase inhibitor (TKI) for the same actionable mutation count as 1 line of therapy. Maintenance therapy is not considered a separate line of therapy. Adjuvant and neoadjuvant therapies count as 1 line of therapy if given within 6 months before study entry.
d. Subjects without any actionable gene alteration: must have progressed on (or be considered ineligible for), or be intolerant to, platinum-based chemotherapy and immune checkpoint inhibitor (as monotherapy or in combination with chemotherapy).
e. Subjects with actionable gene alterations (other than EGFR) for which immune checkpoint inhibitor therapy is not standard of care (e.g., anaplastic lymphoma
kinase [ALK] translocation): must have progressed on (or be considered ineligible for), or be intolerant to, anticancer therapy targeting driver gene alterations and
platinum-based chemotherapy.
f. Subjects with actionable gene alterations (other than EGFR) for which immune checkpoint inhibitor is standard of care: must have progressed on (or be considered ineligible for), or be intolerant to, anticancer therapy targeting driver gene alternation and platinum-based chemotherapy, and also progressed on (or be considered ineligible for) or be intolerant to immune checkpoint inhibitor (as monotherapy or in combination with platinum-based chemotherapy).
3. Part 2:
a. Cohort A:
i. Have histologically or cytologically confirmed locally advanced, recurrent (and not a candidate for curative therapy), or metastatic non-squamous NSCLC.
ii. Tumor sample with high cMET expression by IHC (3+ with tumor cell positivity of ≥50%) confirmed by central laboratory testing.
b. Cohort B:
i. Have histologically or cytologically confirmed locally advanced, recurrent (and not a candidate for curative therapy), or metastatic non-squamous NSCLC.
ii. Tumor sample with intermediate cMET expression by IHC (3+ with tumor cell positivity of ≥ 25% - <50%) confirmed by central laboratory testing.

c. Cohort C:
i. Have histologically or cytologically confirmed locally advanced, recurrent (and not a candidate for curative therapy), or metastatic squamous NSCLC.
ii. Tumor sample with cMET overexpression by IHC (2+ with tumor cell positivity of ≥ 25%) confirmed by central laboratory testing.
d. Cohort D:
i. Have histologically or cytologically confirmed locally advanced, recurrent (and not a candidate for curative therapy), or metastatic NSCLC.
ii. Tumor sample that does not meet cMET IHC entry criteria for Cohorts A and B (for subjects with non-squamous NSCLC) and C (for subjects with squamous
NSCLC) based on central laboratory testing.
iii. Known MET amplification or exon 14 skipping mutations, respectively, performed in a CLIA-certified laboratory in the US or equivalently accredited diagnostic laboratory outside the US.
iv. Subjects with MET exon 14 skipping mutations must have received MET TKI therapy if available and considered standard of care.
e. Cohort E:
i. Have histologically or cytologically confirmed locally advanced, recurrent (and not a candidate for curative therapy), or metastatic NSCLC.
ii. Evidence of cMET expression by IHC as documented in medical records.
Evidence of negative cMET expression by IHC would be excluded.
iii. Has previously received and had disease progression following either a cMET-targeted ADC or antibody therapy. Must have been on the cMET-targeted ADC
or antibody therapy for at least 12 weeks before progression and did not discontinue treatment due to intolerable toxicity.
For all subjects enrolled in Part 1 and Part 2:
4. Subject has at least 1 measurable lesion per RECIST 1.1.
5. ECOG performance status 0 or 1; see Appendix D.
6. Adults aged ≥18 years at time of informed consent.
7. Resolution of acute effects of prior therapy or surgical procedures to ≤ Grade 1 or baseline (except alopecia, stable immune related toxicity such as hypothyroidism on hormone replacement, adrenal insufficiency on ≤10 mg daily prednisone [or equivalent], or anemia).
8.Cardiac left ventricular ejection fraction (LVEF) ≥50% by either echocardiogram (ECHO) or MUGA scan.
9.Adequate organ function as defined as:
a. Absolute neutrophil count (ANC) ≥1500 cells/mm3(without growth factors within 1 week of first dose of study drug administration).
b. Platelet count ≥75,000/mm3(Platelet transfusion not allowed within 1 week prior to first dose of study drug administration).
c. Hemoglobin ≥9 g/dL (RBC transfusion not allowed within 1 week prior to first dose of study drug administration).
d. International normalized ratio (INR) aPTT and prothrombin time (PT) ≤1.5 × institution's ULN. Subjects on stable anticoagulant dose are permitted to enroll.
e. Calculated creatinine clearance >30 mL/min as calculated by the Modified Cockcroft-Gault formula. Refer to Appendix E and Section 5.1.
f. Total bilirubin ≤ 1.5 × ULN, ≤ 2.0 × ULN for subjects with Gilbert syndrome.
g. AST and ALT ≤2.5 × ULN for subjects without liver metastases. For subjects with liver metastases, AST and ALT ≤5 × ULN.
h. Alkaline phosphatase ≤1.5 × ULN unless clearly attributable to a non-hepatic source, e.g., bone metastases.
i. Serum albumin ≥3.0 g/dL.
j. Hemoglobin A1c (HbA1c) <7.5%. Diabetic subjects must be on a stable dose of antidiabetic medications (for ≥ 4 weeks prior to first dose of study drug).

10. For women of childbearing potential and men with partners of childbearing potential, agreement to use a highly effective method of birth control for the duration of the study treatment and for at least 6 months after the last dose of study drug. See Appendix A.
11. Able to provide informed consent, and willing and able to comply with study protocol requirements.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Subjects who meet any of the following exclusion criteria will be excluded from this study:
1. NSCLC with adeno-squamous histology (for Cohorts A, B, and C only; subjects with NSCLC with adeno-squamous histology are allowed in Cohorts D and E).
2. Radiation to the lung within 6 weeks prior to screening. For all other sites (except lung and brain), therapeutic or palliative radiation within 2 weeks of the first dose of study drug. Must have recovered from all radiation-related toxicity.
3. Major surgery within 28 days before first dose of study drug administration.
4. Systemic anticancer therapy including investigational drugs, within the lesser of 28 days or 5 half-lives of the prior therapy before starting study drug (14 days or 5 half-lives for small molecule targeted therapy).
Concurrent use of hormonal therapy for breast cancer or prostate cancer is permitted.
5. Previously received cMET-targeted antibody or ADC, bicycle, or small peptide therapies targeting cMET.
Note: For Cohort E: Subjects will have previously received and progressed on either cMET-targeted ADC or antibody; however, they must not have been intolerant to the cMET-targeted ADC or antibody therapy.
6. Use of any concomitant or prohibited therapies outlined in Section 7.6.
7. Untreated, uncontrolled CNS metastases. Subjects with CNS metastases who have had surgical resection or have received radiation therapy to all known sites of CNS disease ending at least 4 weeks prior to first dose of study drug are eligible if:
a. There is no evidence of disease progression after at least 2 weeks after the end of definitive therapy; and
b. The subject is neurologically stable and either off or on a non-increasing dose (in the past 2 weeks) of systemic steroids.
8. Known history of human immunodeficiency virus (HIV) infection.
9. Untreated hepatitis B virus (HBV) or hepatitis C virus (HCV) infection.
a. HBV: Subjects with serological evidence of chronic HBV infection should have an HBV viral load below the limit of quantification to be eligible. In addition, subjects with positive HBsAg should be on anti-HBV therapy at enrollment and while receiving MYTX-011.

b. HCV: Subjects with history of HCV infection should have completed curative antiviral treatment and have HCV viral load below the limit of quantification.
10. Myocardial infarction, unstable angina, PTCA or CABG or cerebrovascular event (stroke or transient ischemic attack [TIA]) within 6 months before first dose of study drug, symptomatic congestive heart failure (New York Heart Association [NYHA] > Class II; see Appendix B), or ventricular arrhythmias requiring treatment.
11. Elevated corrected QT interval (QTc) >480 ms based on Fridericia's correction formula.
12. History of interstitial lung disease or pneumonitis that required treatment with systemic steroids or evidence of active interstitial lung disease or pneumonitis. A history of prior radiation pneumonitis in the radiation field (fibrosis) is permitted.
13. Subject requires systemic steroid therapy: prednisone 10 mg daily or equivalent. Inhaled steroids or topical steroid use is permitted.
14. Clinically significant systemic illness that could pose undue risk to the subject or confound the ability to interpret study results.
15. Active infection requiring IV antibiotics, antivirals, or antifungal medication within 14 days of Cycle 1 Day 1.
16. Neuropathy > Grade 1 for any reason.
17. History of cirrhosis, hepatic fibrosis, esophageal or gastric varices, or other clinically significant liver disease.
18. Active or chronic corneal disorder such as primary or secondary Sjögren's syndrome, severe dry eye disease (any cause), history of corneal transplantation, ocular chronic graft-versus-host disease, active corneal infection (including herpetic keratitis) neurotrophic keratopathy or other forms of severe ocular surface disease, severe visual impairment (due to any cause), active ocular conditions requiring ongoing treatment/monitoring such a wet age-related macular degeneration, active diabetic retinopathy with macular edema, or monocular status or severe visual impairment in 1 eye.
19. History of another malignancy within the past 3 years prior to screening except adequately treated basal cell or squamous cell skin cancer, carcinoma in situ of the breast or cervix, or organ-confined prostate cancer.
20. Known active coronavirus disease 2019 (COVID-19) infection determined by positive COVID-19 antigen test or PCR test, or has signs and symptoms associated with COVID-19 within 14 days prior to first dose of study drug. Subjects must have a negative test and/or no further signs and symptoms associated with COVID-19 within 14 days of administration of first dose of study drug. Subjects who screen fail due to COVID-19 may be rescreened after they have recovered from COVID-19 after discussion with the Sponsor Medical Monitor.
21. Known hypersensitivity to monoclonal antibodies.
22. Pregnant (positive pregnancy test at screening) or lactating female.
23. Known hypersensitivity to MYTX-011 or any of its excipients.

Date of first enrolment
23/03/2023

Date of final enrolment
31/10/2027

Locations

Countries of recruitment
Australia

France

Korea, South

Spain

Taiwan

United States of America

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Mythic Therapeutics

Funder(s)

Funder type
Industry

Funder Name
Mythic Therapeutics

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date